United States Department of the Interior

FISH AND WILDLIFE SERVICE
Ecological Services
Nebraska Field Office
203 West Second Street
Grand Island, Nebraska 68801

February 10, 2006

Greg Ibach, Director
Nebraska Department of Agriculture
P.O. Box 94947
Lincoln, NE 68509-4947

Dear Mr. Ibach:

Mr. Tim Creger, the Pesticide Program Manager for your department, provided our office with an electronic copy of the January 20, 2006, letter addressed to you by Mr. Schmit of LiphaTech. Mr. Schmit's letter was in response to our January 13, 2006, letter, which requested that the Nebraska Department of Agriculture (NDA) reject the Section 24(c) request to register Rozol® for the control of black-tailed prairie dogs (*Cynomys ludovicianus*) in Nebraska. Recognizing that you will be making a decision regarding this request, the U.S. Fish and Wildlife Service (Service) believes that it is necessary to respond to the errors and misinterpretations in Mr. Schmit's letter.

1. There is not a valid special local need (SLN) for Rozol.
LiphaTech Comment: The "special local need" is established by the large number of formal requests from the user community and their trade organizations, and the U.S. Environmental Protection Agency (EPA) has already agreed that a "special local need" exists.

Service Response: The Service is not convinced that the need described for Rozol in Nebraska satisfies the definition for a "special local need" (SLN) according to EPA's Office of Pesticide Programs policy guidance on Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 24(c) Registrations (EPA 1996). According to the guidance, there are four situations whereby a state can document a SLN (EPA 1996). The Service maintains that none of these four situations have been sufficiently proven, including the claim that Rozol is less toxic than zinc phosphide. Finally, the guidance document recognizes that "a 24(c) registration may be needed in multiple states based on local needs in each state" but specifies that "in this situation, states should provide an explanation as to why the situation is a 'special local need'" (EPA 1996). Therefore, the existence of a SLN in Kansas is not sufficient justification for a SLN in Nebraska. In conclusion, the Service maintains that there is not a valid SLN for Rozol in Nebraska.

2. There is not enough information about Rozol's impacts to nontarget wildlife species.

LiphaTech Comment: There is a large amount of information about wildlife hazards of chlorophacinone available, as summarized and analyzed by EPA, that shows little risk to nontarget animals.

Service Response: There are crucial data gaps in the scientific literature on the toxicity of Rozol to nontarget wildlife species. EPA identifies some of the important data gaps and other factors that contribute to the uncertainty of its risk assessment (EPA 2004a). These include:

> **"(1) missing data, including acute, chronic, and secondary toxicity…; (2) the variable quality and quantity of existing data on metabolism and retention times in rodents and nontarget species; … (4) information on the … likelihood of [birds and nontarget mammals] finding and consuming bait or poisoned primary consumers in the various use areas; … (6) not accounting for the impacts of sublethal effects on reproduction and nontarget mortality (e.g., clotting abnormalities, hemorrhaging, stress factors…); (7) not accounting for bioaccumulation of repeated sublethal exposures to bait or poisoned rodents utilized as food by predators and scavengers; …" (EPA 2004a).**

The majority of the uncertainty factors and data needs identified by EPA in its risk assessment apply to chlorophacinone, the active ingredient in Rozol (EPA 2004a). For example, the few secondary toxicity studies summarized by EPA in its risk assessment (EPA 2004a) are statistically inadequate to draw conclusions on Rozol's secondary toxicity to nontarget wildlife species. Additionally, although Rozol is known to be highly toxic to freshwater invertebrates (EPA 1998), there have not been any studies on the primary and secondary risk of Rozol to terrestrial invertebrates, such as the federally endangered American burying beetle (*Nicrophorus americanus*). Finally, the "real-world" examples that LiphaTech cited rely on incident reports and carcass-detection monitoring efforts. In a February 28, 2005, comment letter to EPA regarding EPA's risk assessment document, the Service states:

> **"Incident reports are believed to represent a small fraction of the actual mortality for any given pesticide (Vyas 1999). … Carcass-detection studies have found that even when searches are performed on known carcasses, a significant percentage will never be found due to scavenging, location in remote, inaccessible areas, or size or coloration that renders the carcass inconspicuous (Vyas 1999)." (Document ID Number EPA-HQ-2004-0033-171 of the EPA-HQ-2004-0033 docket, available from <http://www.regulations.gov>).**

The uncertainties in EPA's risk assessment and the unknown toxicity to Federal trust resources, such as migratory birds and threatened and endangered species, are the primary concerns that the Service has with Rozol. Thus, the Service recommends that NDA reject the proposed 24(c) registration of Rozol to control black-tailed prairie dogs (BTPDs) in Nebraska.

3. In-burrow application of Rozol may not effectively minimize nontarget wildlife exposure.

LiphaTech Comment: In-burrow application of Rozol is safer for nontarget wildlife than the application practices currently in use for zinc phosphide.

Service Response: LiphaTech has not provided sufficient information to support this claim (see our comments above regarding reliability of incident reports). Specifically, the Service has concerns that reliable carcass searches have not been conducted in a sufficient number of studies to conclude that intoxicated BTPDs or poisoned BTPD carcasses will not be present above ground. Additionally, many of these carcass searches have not been conducted with short-enough time intervals to ensure that carcasses are detected prior to removal by predators and scavengers.

In our previous letter, and during the Pesticide Board meeting on January 25, 2006, we mentioned the Rosebud Indian Reservation incident where Rozol was illegally used to control BTPDs and 300 to 400 BTPD carcasses were removed from the surface of the BTPD colony. This incident demonstrates that not all sick BTPDs will move to their burrows. Sick or dead BTPDs that occur above ground can present a significant risk of secondary poisoning to mammalian and avian predators or scavengers. Given the recognized paucity of tests regarding secondary poisoning of animals that consume Rozol-poisoned prairie dogs, it is inappropriate to assert that Rozol is safer for nontarget animals. Additionally, the few studies that have been done indicate mammals are highly susceptible to secondary poisoning from Rozol-poisoned carcasses and, thus, indicate greater secondary effects for Rozol compared to zinc phosphide. This may effectively negate much of the advantage that in-burrow application would have to minimize nontarget wildlife exposure. As for zinc phosphide, concerns for acute exposure to nontarget wildlife species can be minimized by using tamper-resistant bait stations according to label instructions or by applying treated bait only when and where pre-baiting has indicated that only BTPDs are feeding on the bait.

4. Rozol has not been adequately proven to be an effective control for BTPD.
LiphaTech Comment: The efficacy of Rozol to control prairie dogs has been properly and adequately established, as EPA has reviewed efficacy data and determined them to be acceptable.

Service Response: The actual efficacy of Rozol is highly variable and current studies do not present efficacy results that are higher or more reliable than current federally registered pesticides used to control BTPDs. Additionally, LiphaTech is incorrect in stating that the EPA efficacy review document determined Rozol's efficacy data to be acceptable. EPA's efficacy document actually contained much criticism of the efficacy results from the existing Rozol studies (EPA 2004b).

5. The Kansas 24(c) SLN permit ... may not have been properly evaluated and reviewed prior to approval. ...
LiphaTech Comment: The Kansas SLN application was thoroughly reviewed both by the Kansas Department of Agriculture and by the EPA.

Service Response: The Service is concerned that the Kansas SLN application was not properly evaluated and reviewed. These concerns are supported by the same EPA efficacy document that LiphaTech cited as providing a thorough review of the Rozol SLN

application (EPA 2004b). In our previous January 13, 2006, letter, we quoted sections of the EPA efficacy document that demonstrated EPA's concerns with the Kansas SLN application. Additionally, the Service is uncertain where LiphaTech obtained their information that led them to conclude that "the SDDA [South Dakota Department of Agriculture] did NOT `reject a request in 2005 for a 24(c) SLN registration of Rozol pocket Gopher Bait to control BTPDs.'" We obtained our information directly from the South Dakota Department of Agriculture and have a copy of the rejection letter that the SDDA sent to individuals who requested the SDDA's approval of a 24(c) registration of Rozol to control BTPDs in South Dakota. Additionally, we have a copy of a letter from SDDA to their county weed/pest supervisors and extension educators informing them of the SDDA's denial of the Rozol 24(c) request. Copies of both SDDA letters are being enclosed for your review.

6. In-burrow application and carcass pickup are required label restrictions that are essential to protect wildlife resources. These restrictions would likely negate perceived labor and cost benefits of Rozol.

LiphaTech Comment: Rozol has now been widely used in Kansas, and both private and public users (county-based BTPD control programs), and applicators have been satisfied that it has lower application costs and better efficacy than existing alternatives.

Service Response: The Service has recently obtained information on the cost to control BTPDs from the Kansas State University, Ellis County Extension Office. Using 35 burrows/acre as an average, the Ellis County Extension Office determined that it costs $4.52/acre for Zinc Phosphide Oats and $6.17/acre for Rozol (KSU 2005). This cost estimate included labor ($10.00/hour) and materials (KSU 2005). This information from Kansas, contradicts the claim that Rozol has lower application costs than existing alternatives.

The Service appreciates the opportunity to present our viewpoint and concerns regarding Rozol at the January 25, 2006, meeting of the Nebraska Pesticide Board. At that meeting, the Board decided to recommend that the Section 24(c) request to register Rozol be approved for the control of BTPDs in Nebraska with an expiration data of March 15, 2008. Several of the board members believed that the approval of the 24(c) application request would provide an opportunity to conduct further toxicity studies on Rozol to address the existing gaps in toxicity data. However, no positive commitment was made by LiphaTech or any other organization to fund such studies. The Service also identified that the 24(c) registration was unnecessary to conduct further toxicity studies on Rozol. The existing 24(c) registration in Kansas would allow for further field studies. Additionally, most secondary toxicity studies are performed in laboratory settings, which do not need a 24(c) registration to conduct studies in a state (instead, they can apply for an experimental use registration).

If NDA decides to approve the 24(c) application for Rozol to control BTPDs despite the Service's recommendations, we do have some suggestions for modifications to the Nebraska Rozol label that would help alleviate some of our concerns.

1. The Service strongly recommends that the Rozol label be changed to a Restricted Use Pesticide label. This would ensure that the label is properly followed with regard to application and proper carcass collection and disposal.

2. We mentioned in our previous January 13, 2006, letter that the bait application language seemed very confusing. Additionally, the Service has concerns that any bait visible from the surface would serve as an attractant to nontarget wildlife species, especially granivores or omnivores that could get into the BTPD burrow. Accordingly, the Service recommends that the bait application language be changed to require that bait be placed at least six inches into the burrow and that bait is not visible from the ground surface.

3. The current proposed label for Nebraska states that "carcasses buried on site must be in holes dug at least 18 inches deep." Members of the Pesticide Board stated during the January 25, 2006, meeting that this depth was not adequate to ensure that carcasses would not be dug up by predators and/or scavengers. Accordingly, the Service recommends that the Rozol label require that carcasses be burned (with approval of an appropriate burn permit, if necessary). If NDA objects to having the carcasses burned, then the Service recommends that the carcass depth on the label be increased to at least three feet deep.

4. The label does not have any specific information or instructions on the frequency and length of time that BTPD carcasses should be collected and properly disposed. Predators and scavengers are active daily, especially between the hours of dusk and dawn, but at other times of the day as well. Additionally, EPA has indicated that it can take up to ten days after bait application for death to occur from chlorophacinone (EPA 1998). Therefore, the Service recommends that the label require that carcass searches be conducted at a minimum of once per day. The label also should specify the time of day for carcass searches and the length of time spent on each search. The best time for a daily search would be between late afternoon and dusk. The length of time spent on each search should be adequate to carefully search the entire BTPD town that was "treated" with the Rozol bait. Finally, the Service recommends that the label specify that carcass searches be started the day after bait application and continue for a total of 12 days.

5. The label should specifically state that the product registration expires on March 15, 2008, and that it is illegal to use the product after that time.

6. Finally, the label should caution against the use of the product in areas where either state or federally listed threatened and endangered species may occur. The Nebraska Game and Parks Commission should be contacted for a complete list of state threatened and endangered species that occur in the proposed project area. Additionally, the Nebraska Field Office of the U.S. Fish and Wildlife Service should be contacted for a complete list of Federal threatened and endangered species that occur in the proposed project area. Our main telephone number (308-382-6468) can be provided on the label for contact information. Internet sites should not be relied upon for listed species information because they are commonly incorrect and/or not up to date.

   The Service would prefer that the label stipulate that Rozol should not be used when state or federally listed threatened and endangered species may occur in the proposed project area. However, if chemical control of BTPDs is still planned, the Service recommends that pre-treatment monitoring be required to determine what threatened and endangered species occur in the BTPD town and the most likely routes of exposure to these species. The results of the monitoring should be used to determine the appropriate rodenticide to use in order to minimize the potential exposure to threatened and endangered species, along with other nontarget species.

The Service also recommends that NDA work with LiphaTech to obtain some kind of arrangement that LiphaTech will fund additional studies on Rozol during the two-year time frame that the Pesticide Board recommended for the Rozol 24(c) registration and label in Nebraska. It appeared that several board members left the January 25, 2006, meeting with the understanding that some additional toxicity studies will be conducted over the next two years. As we mentioned above, a formal commitment or agreement to future arrangements to fund additional studies was not made by LiphaTech during the Pesticide Board meeting. These studies should investigate the secondary toxicity of Rozol to birds, mammals, and terrestrial invertebrates along with the acute toxicity to terrestrial invertebrates. Additionally, studies should also be conducted on reproductive effects, sublethal effects, and the number of BTPD carcasses that die above ground after a Rozol treatment. Whenever possible, EPA protocols should be used. The Service also is willing to participate with other interested parties in the review of study designs to help ensure that the studies and resulting data meet the needs of decision makers. Information from these studies would help address the majority of the Service's concerns with Rozol and would aid EPA's continuing assessment of this rodenticide.

In conclusion, the Service respectfully recommends that NDA not issue the 24(c) SLN registration for Rozol to control BTPDs in Nebraska. If NDA does decide to approve the 24(c) registration, we respectfully submit our comments and recommendations to the Rozol label. We appreciate your consideration of our concerns and our comments in response to LiphaTech's January 20 letter. If you have any further questions on the information in this letter or any of our comments and viewpoints, we would be happy to meet and further discuss this issue with you and members of your staff. Questions or arrangements for a meeting may be referred to Ms. Christina Lydick of my staff at christina_lydick@fws.gov or (308) 382-6468, extension 14.

Sincerely,

Sharon Whitmore

Sharon Whitmore
Acting Nebraska Field Supervisor

Enclosures

Literature Cited

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cc: FWS Regional Office; Denver, CO (Attn: Larry Gamble)
FWS Kansas Field Office; Manhattan, KS (Attn: Mike LeValley)
FWS South Dakota Field Office; Pierre, SD (Attn: Pete Gober)
FWS Montana Field Office; Helena, MT (Attn: Mark Wilson)
FWS Montana Sub-Office; Billings, MT (Attn: Lou Hanebury)
EPA Region 7; Kansas City, KS (Attn: Jamie Green)
EPA Headquarters; Washington, D.C. (Attn: John Hebert)
NGPC; Lincoln, NE (Attn: Kirk Nelson)
NGPC; Lincoln, NE (Attn: Mike Fritz)
Nebraska Department of Agriculture; Lincoln, NE (Attn: Tim Creger)

SOUTH DAKOTA DEPARTMENT OF AGRICULTURE
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523 East Capitol Ave., Foss Building
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March 24, 2005

County Weed/Pest Supervisors and Extension Educators:

As you may be aware, the Department of Agriculture was requested to approve a Special Local Need registration of Rozol Pocket Gopher Bait for prairie dog control.

After giving these petitions careful consideration, the request was denied. Overall, we believe that Rozol is not a viable tool for the control of prairie dogs. For your information and so that you may understand the reasons the request was denied, I am enclosing a copy of the letter that was sent to the petitioners of the Special Local Need label.

If you have any questions, please contact me at (605) 773-4432.

Sincerely,

Brad D. Berven, Administrator
Office of Agronomy Services

523 East Capitol Avenue, Pierre, SD 57501-3182
(605) 773-3375 (605) 773-5926 FAX

OFFICE OF THE SECRETARY

March 23, 2005

Dear

Thank you for your recent request for the Special Local Need (24c) registration of Rozol Pocket Gopher Bait for control of prairie dogs. We have reviewed the information pertaining to this product and the legal basis for such a registration. Upon completing this review we have determined that we can not pursue the registration you requested. The reasons for this decision are as follows:

1) **Legality** - This use is not eligible, under federal regulation, as a Special Local Need registration because there are other federally registered products available for prairie dog control. Issuance of this registration could be determined to be in violation of federal regulation and could jeopardize our authority to issue registrations for true "special local need" uses.

2) **Efficacy** – Our review of the available data indicates that Rozol has provided a level of control of 68% in baiting trials. (Lee, 2002) Zinc phosphide products have been demonstrated to be significantly more effective at controlling prairie dogs than Rozol, when used as directed, often over 90%. (Tietjen, 1976) Further, Rozol requires several feedings, and possibly follow-up treatments, to be effective.

3) **Environmental Hazards** – While zinc phosphide products can present a hazard to some bird species, Rozol possesses a significant secondary poisoning hazard that zinc phosphide does not. As a result, the treatment site must be monitored for dead prairie dogs and these animals collected and buried at least 18 inches deep. As a result of these hazards, we believe the overall environmental hazard for Rozol is increased over zinc phosphide products. Regarding use classification, all above ground uses of prairie dog toxicants are to be designated as restricted uses.

4) **Cost** – Given the cost of labor, number of pre and post treatment visits necessary and the cost of the bait, we estimate the per acre cost of Rozol treatments to be at least 50% higher than zinc phosphide treatments.

We suggest you contact the maker of Rozol Pocket Gopher Bait, Liphatech at (414) 351-1476 and request that they pursue a regular registration for prairie dog control with EPA. If you would like to discuss the information used to make this determination, please contact Brad Berven of my staff at (605) 773-4432.

Sincerely,

Larry Gabriel
Secretary of Agriculture